Objective measures of functional impairment for degenerative diseases of the lumbar spine: a systematic review of the literature

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Abstract: BACKGROUND CONTEXT: The accurate determination of a patient's functional status is necessary for therapeutic decision-making and to critically appraise treatment efficacy. Current subjective patient-reported outcome measure (PROM)-based assessments have limitations and can be complimented by objective measures of function. PURPOSE: To systematically review the literature and provide an overview on the available objective measures of function for patients with degenerative diseases of the lumbar spine. STUDY DESIGN/SETTING: Systematic review of the literature. METHODS: The PRISMA guidelines were followed. Two reviewers independently searched the PubMed, Web of Science, EMBASE and SCOPUS databases for permutations of the words "objective", "assessment", "function", "lumbar" and "spine", including articles on human subjects with degenerative diseases of the lumbar spine that reported on objective measures of function, published until September 2018. No funding was received. The authors report no conflicts of interest. RESULTS: Of 2389 identified articles, 82 were included in the final analysis. There was a significant increase of 0.12 per year in the number of publications dealing with objective measures of function since 1989 (95% CI 0.08-0.16, $p<0.001$). Some publications studied multiple diagnoses and objective measures. The US was the leading nation in terms of scientific output for objective outcome measures (n=21; 25.6%), followed by Switzerland (n=17; 20.7%), Canada, Germany and the United Kingdom (each n=6; 7.3%). Our search revealed 21 different types of objective measures, predominantly applied to patients with lumbar spinal stenosis (n=67 publications; 81.7%), chronic/unspecific low back pain (n=28; 34.2%) and lumbar disc herniation (n=22; 26.8%). The Timed-Up-and-Go (TUG) test was the most frequently applied measure (n=26 publications; 31.7%; cumulative number of reported subjects: 5181), followed by the Motorized Treadmill Test (MTT; n=25 publications; 30.5%, 1499 subjects) and with each n=9 publications (11.0%) the Five-Repetition Sit-To-Stand test (5R-STS; 955 subjects), as well as accelerometry analyses (336 subjects). The reliability and validity of many of the less-applied objective measures was uncertain. There was profound heterogeneity in their application and interpretation of results. Risk of bias was not assessed. CONCLUSIONS: Clinical studies on patients with lumbar degenerative diseases increasingly employ objective measures of function, which offer high potential for improving the quality of outcome measurement in patient-care and research. This review provides an overview on available options. Our findings call for an agreement and standardization in terms of test selection, conduction and analysis to facilitate comparison of results across cohorts.

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Objective measures of functional impairment for degenerative diseases of the lumbar spine: a systematic review of the literature

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Abstract

Background Context: The accurate determination of a patient's functional status is necessary for therapeutic decision-making and to critically appraise treatment efficacy. Current subjective patient-reported outcome measure (PROM)–based assessments have limitations and can be complimented by objective measures of function.

Purpose: To systematically review the literature and provide an overview on the available objective measures of function for patients with degenerative diseases of the lumbar spine.

Study Design/Setting: Systematic review of the literature.

Methods: The PRISMA guidelines were followed. Two reviewers independently searched the PubMed, Web of Science, EMBASE and SCOPUS databases for permutations of the words "objective", "assessment", "function", "lumbar" and "spine", including articles on human subjects with degenerative diseases of the lumbar spine that reported on objective measures of function, published until September 2018. No funding was received. The authors report no conflicts of interest.

Results: Of 2389 identified articles, 82 were included in the final analysis. There was a significant increase of 0.12 per year in the number of publications dealing with objective measures of function since 1989 (95% CI 0.08–0.16, $p<0.001$). Some publications studied multiple diagnoses and objective measures. The US was the leading nation in terms of scientific output for objective outcome measures (n=21; 25.6%), followed by Switzerland (n=17; 20.7%), Canada, Germany and the United Kingdom (each n=6; 7.3%). Our search revealed 21 different types of objective measures, predominantly applied to patients with lumbar spinal stenosis (n=67 publications; 81.7%), chronic/unspecific low back pain (n=28; 34.2%) and lumbar disc herniation (n=22; 26.8%). The Timed-Up-and-Go (TUG) test was the most frequently applied measure (n=26 publications; 31.7%; cumulative number of reported subjects: 5181), followed by the Motorized Treadmill Test (MTT; n=25 publications; 30.5%, 1499 subjects) and with each n=9 publications (11.0%) the Five-Repetition Sit-To-Stand test (5R-STS; 955 subjects), as well as accelerometry analyses (336 subjects). The reliability and validity of many of the less-applied objective measures was uncertain. There was profound heterogeneity in their application and interpretation of results. Risk of bias was not assessed.

Conclusions: Clinical studies on patients with lumbar degenerative diseases increasingly employ objective measures of function, which offer high potential for improving the quality of outcome measurement in patient-care and research. This review provides an overview on available options. Our findings call for an agreement and standardization in terms of test selection, conduction and analysis to facilitate comparison of results across cohorts.

Key words:

Objective functional impairment; disability; objective outcome measure; physical function; systematic review; functional test

Abbreviations:

5R-STS – Five-Repetition Sit-To-Stand

6MWT – 6-minute walking test

6MWD - 6-minute walking distance

AST – alternative step test

BMI – body mass index

DDD – degenerative disc disease

DTFS – distance to first symptoms

EQ-5D – Euro-Qol 5 D

GPS – Global Positioning System

hrQoL – health-related quality of life

ICC – intraclass correlation coefficient

IF – impact factor

kpm – kilogram force meter (Kilopondmeter)

LBP – low back pain

LDH – lumbar disc herniation

LSS – lumbar spinal stenosis

m - meters

MCID – minimum clinically important difference

min - minutes

MTT – Motorized Treadmill Test

ODI – Oswestry disability index

OFI – objective functional impairment

PCS – physical component summary

PICOS – participants, interventions, comparators, outcomes, and study design

PROMs – patient reported outcome measures

RCT – randomized controlled trial

RMDI – Roland-Morris disability index

rpm – revolutions per minute

TAT – total ambulation time

TTFS – time to first symptoms

TUG – Timed Up and Go test

s - seconds

SD – standard deviation

SM – standard error of measurement

SF-12 – short-form 12

SPWT – self-paced walking test

SSSQ – Swiss Spinal Stenosis Questionnaire

SWT – Shuttle Walking Test

VAS – visual analog scale

VCF – vertebral compression fracture

W – Watt (unit of power)

WC – weight carrying

Introduction

The goals of surgical interventions for degenerative diseases of the spine are relieving pain, and improving function and health-related quality of life (hrQoL).[1] Choice of surgical intervention is complex and depends on many factors. Knowledge of disease natural history is required, since pain (and even motor deficit) may respond to conservative therapy.[2] It is essential to assess pain, functional limitations and reduction of hrQoL as accurately as possible, since this information serves as a basis for decision-making for or against surgical treatment. Baseline functional status may be used as a reference, against which the success or failure of any treatment will be measured.

An important and necessary evolution has taken place in the last decades, away from the subjective assessment of the treating physician towards a more patient-centered approach.[3] Focus is now on subjective patient-reported generic or disease-specific outcome measures (PROMs) for disability and hrQoL, such as e.g., the Oswestry disability index (ODI), the Roland-Morris disability index (RMDI) or the Short-Form 12/36 (SF-12/SF-36). Furthermore, generic and disease-specific objective measures of function are gaining increasing attention, adding a further dimension to the comprehensive patient evaluation. The possibilities of broadly-available new technologies such as smartphones equipped with accelerometers or global positioning systems (GPS) have opened additional venues for disability and outcome measurement in research and healthcare.

As the number of reports pertaining to potential objective measures of function continues to grow, the aim of this systematic literature review was to provide an overview on currently available objective measures of function, applicable to patients suffering from degenerative pathologies of the lumbar spine.

Material and methods

The guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) were followed for conducting this systematic review.[4]

Study selection criteria

We included articles of human subjects written in English, German or French that met the following criteria: reporting of one or several objective measures of function, applied to human patients with degenerative diseases of the lumbar spine. We defined objective measures of function as being (1) based on a task to be performed by the patient, (2) evaluated using an objective assessment of the patients' performance on that task (i.e. time taken, repetitions, etc.), (3) rated by an observer/machine instead of the patient him/herself, and (4) based on a standardized testing protocol. We did not consider widespread objective methods used in orthopedics that measure only certain aspects of the human body, e.g., joint mobility with a goniometer, muscle strength with the help of a Newton meter, or radiological parameters (e.g. Cobb angle for scoliosis, parameters of sagittal balance, diameter of the spinal canal in the axial magnetic resonance imaging (MRI)). Furthermore, the search was focused strictly on outcome measures for patients with degenerative diseases of the lumbar spine; those applied for trauma (e.g., spinal cord injury), spinal oncology, degenerative cervical pathologies or cranial neurosurgery were not included.

Database search and study extraction

A systematic literature was conducted in PubMed, Web of Science, EMBASE and SCOPUS databases, including articles published until September 2018. We searched for permutations of the words “objective”, “assessment”, “function”, “lumbar” and “spine” in each database’s search engine (see Appendices C-F). Full-text papers of which the title and abstract met the eligibility criteria (Table 1) were rigorously assessed to determine inclusion. References from each full-text article were similarly re-viewed for inclusion eligibility. The study screening and data extraction were independently performed by two reviewers (M.N.S. & A.L.H.), and any discrepancies were resolved by discussion between those two, or with the entire research group.

Data collection

Reference data such as the study objective, number of included subjects, cohort and disease type studied in general, as well as specifically for each type of applied objective measure were extracted from the selected articles, together with the study design, year of publication,

country of origin (or country of main data generation in case of international collaborations), journal name and the journal's 2017 impact factor (IF, as provided by Thomson-Reuter, whenever available). The latter was done to estimate the scientific robustness and value of each outcome measure. We extracted the method of application, as well as any information regarding its test qualities. The primary objective of each study was characterized as either a study dedicated to a) exploring qualities of the objective measure (e.g., reliability, validity, responsiveness, minimum clinically important difference (MCID), satisfaction), b) characterizing a certain disease by means of the objective measure (e.g., comparing the functional status of patients with or without spondylolisthesis) or c) investigating a therapeutic effect (applying the objective measure to compare outcomes between treatment groups).

Quality assessment of selected studies & establishment of level of evidence

As we did not intend to carry out a meta-analysis and no valid tools were available to evaluate objective functional tests, we desisted from systematically evaluating quality, level of evidence and risk of bias of each included study/functional test.

Analysis

Quantitative statistical analysis was only possible to a limited extent, due to the significant heterogeneity in included studies' aim, design and type of objective test. Whenever feasible, categorical variables were analyzed by Chi-square and continuous variables by two-sample t-tests. Time trends were analyzed by Poisson regression, allowing calculation of robust standard errors as recommended by Cameron and Trivedi.[5] All analyses were conducted using Stata v14.2 (College Station, Texas, USA). P-values < 0.05 on two-tailed hypotheses were considered statistically significant.

Results

Our database search initially yielded 2389 articles. After title and abstract screening, 2301 articles were excluded because they did not meet the inclusion criteria. 88 potentially eligible articles remained, of which 29 duplicates were removed. Further 73 citations were added through backward- and forward citation and hand searching. Thus, 132 articles were retrieved

for full-text analysis, of which 50 were subsequently excluded because they were irrelevant to this study. Ultimately, 82 citations were included in this study (Figure 1). A comprehensive overview on all 82 articles is provided in Supplementary Table 1.

Disease types

Lumbar spinal stenosis (LSS) was by far the disease most frequently studied by objective measures of function (n=67 publications; 81.7%), followed by chronic/unspecific low back pain (LBP; n=28; 34.2%), lumbar disc herniation (LDH; n=22; 26.8%), spondylolisthesis (n=18; 22.0%), deformity (n=4; 4.9%), vertebral compression fracture (VCF; n=1; 1.2%) or other types (n=4; 4.9%).

Time-trend in reporting objective measures of function

There was a profound and significant increase of 0.12 scientific papers per year that included an objective measure of function across the last decades (95% CI 0.08–0.16, $p<0.001$; Figure 2).

Reporting of objective measures of function per country

The USA was the leading nation in terms of overall number of publications that included an objective measure of function (n=21; 25.6%), followed by Switzerland (n=17; 20.7%), Canada, Germany and the United Kingdom (each n=6; 7.3%). A comprehensive overview of the absolute and relative frequency of publications employing an objective measure of function per country is provided in Figure 3.

Reporting of objective measures of function per journal

Spine was the leading journal in terms of overall number of publications that included an objective measure of function (n=19; 23.2%), followed by The Spine Journal (n=8; 9.8%), the European Spine Journal (n=7; 8.5%), Archives of Physical and Medical Rehabilitation (n=4; 4.9%) and Acta Neurochirurgica, the Journal of Neurosurgery: Spine and World Neurosurgery with 3 articles each (3.7%; Supplemental Figure 1).

Objective tests

Our search revealed 21 different types of objective measures of function, for which a comprehensive overview is provided in Table 2, including the absolute and relative frequency of application, study type and disease type for which the measure was applied. The table also summarizes the cumulative and mean number of reported participants per objective measure. The scientific value of each measure is estimated by providing the cumulative and mean impact factor (IF) of the journals that have published articles of each measure. In the table, a brief description of each objective measure is provided. However, many measures were not performed according to uniform and standardized protocols, and instructions given to participants, test protocols and analysis of outcomes profoundly varied across studies for many identified objective measures of function.

The most frequently applied objective measure was the Timed-Up and Go (TUG) test (n=26 publications; 31.7%) with a cumulative number of 5181 reported subjects. This measure also applied for the widest range of disease types: LSS, LDH, LBP, spondylolisthesis, spinal deformity, VCF, and others. We identified 10 articles focusing primarily on characteristics of the TUG test, 11 articles applying the TUG test to study a disease/condition, and 5 articles that applied the TUG test to compare outcomes between two different treatment regimes (Table 2). The TUG test was followed in frequency by the Motorized Treadmill Test (MTT; n=25 publications; 30.5%; 1499 reported subjects) and both the Five-Repetition Sit-To-Stand test (5R-STS; n=9 publications; 11.0%; 955 reported subjects), as well as accelometry analyses (n=9 publications; 11.0%; 336 reported subjects).

Reports applying the 6-minute walking test (6MWT) had the highest cumulative IF (90.73), followed by those applying the TUG test (69.55) and the MTT (65.21).

A comprehensive overview on all metrics for identified objective measures of function is provided in Table 2. The most frequently applied, reproducible, reliable and validated objective measures of function are described in more detail in the following:

The TUG test

The TUG is a simple test that does not require any special equipment except for a chair and 3m of walking space. It has frequently been applied in patients harboring a multitude of

degenerative conditions of the lumbar spine. Here, patients sit on a chair and lean back, with arms resting on the armrests. On the word “Go”, they are asked to get up and walk as fast as possible to a marked line on the floor at 3m distance. At this line, patients turn around (180°), return to the chair and sit back down, as quickly as possible. The time between getting up and sitting down again is recorded in seconds using a stopwatch.[6-8] Besides interpreting raw test times (in seconds (s)), categorizing patients into those with no, mild, moderate or severe “objective functional impairment” (OFI) is possible using age- and sex-standardized cut-off values.[6, 8] Moreover, the calculation of standardized OFI T-scores allows for exact determination of a patient’s functional condition as a deviation from the normal population.[6-10] Working with OFI rather than TUG test raw values prevents bias naturally introduced by the high influence of the variables age and sex on the TUG test.[10-12] A free smartphone app can be utilized for both TUG measurement and automatic OFI calculation (more information in Appendix A).

The TUG test had excellent intra- (intraclass correlation coefficient (ICC) 0.97) and interrater reliability (ICC 0.99), with a standard error of measurement (SEM) of 0.21 and 0.23 sec., respectively.[6] It was shown to discriminate between disability in patients with or without chronic LBP.[13] Among a set of clinical variables, the TUG test result was the one that showed the highest correlation with disability and walking capacity.[14] The convergent validity with PROMs, such as visual analog scale (VAS) back (r=0.25) and leg pain (r=0.29), RMDI (r=0.38) and ODI (r=0.34), as well as SF-12 physical component summary (PCS; r=-0.32) and EQ-5D (r=-0.28) was demonstrated.[6] In surgical candidates with lumbar degenerative disc disease (DDD), convergent validity of the TUG test with PROMs of pain intensity, functional impairment and QoL was even higher after as compared to before the surgical intervention.[9] Various studies demonstrate that the TUG test is sensitive to a patient’s postoperative change in function.[7, 9, 15] A change in the TUG test of at least 3.4s is considered a clinically meaningful change in function (MCID) for patients with lumbar DDD.[7] For single, but especially for repetitive evaluations, patients preferred the TUG test over questionnaire-based assessments.[16]

Considering its high intra-rater reliability, a single trial would be sufficient to measure a participants level of impairment,[6-8] but some studies preferred to calculate the mean of two

or three TUG trials.[13, 17] While one study suggested that a patients' body mass index (BMI) might adversely effect the performance of functional mobility tests,[18] a dedicated report did not find a significant influence of the BMI on the TUG test.[19] Further research indicated little or no influence of a patients' smoking and of the mental health status on the TUG test result,[20, 21] making this test a particularly interesting option for the functional assessment of patients with psychiatric comorbidities that often interfere with PROM-based assessments.[20]

The MTT

For the MTT, patients are instructed to walk on a calibrated treadmill, usually starting on a level surface (0% grade) and at an established protocol speed and time. Participants should not place both hands at the handrails for support, as this can improve their walking capacity by bending forward;[22-25] holding one handrail for balance purposed is usually allowed, however. Pain and/or paresthesia can be measured before and after the test; the time of symptom onset can also be monitored.

Prior studies have proposed to start with 10min at 2mph, increase to 2.5mph for the next 5min, then to 3mph for additional 5min (total of 20min),[26, 27] or to remain at a constant speed of 2–2.5mph for the complete duration of 15 or 30min.[28-34] Other groups had participants walk at maximum, individually selected speed for up to 15 or 30min.[22, 23, 35-37] According to the modified Bruce protocol, two warm-up stages of 3min are followed by incremental increase in speed and gradient.[38-40] Further, other individualized protocols have been used.[25, 41-43] If a participant is unable to tolerate the standard speed and distance, the speed is reduced or the test is ended, if necessary. The test is also stopped when subjects reach a safety endpoint, e.g. 85% of predicted maximal heart rate (220 – age).[39]

Raw test results are the time of onset or significant increase in symptoms (TTFS = time to first symptoms; min and s), the total ambulation time (TAT; min and s), the total distance walked (m), as well as the maximum walking speed (m/s) for protocols that allow individual speed selection.[26, 28, 35, 43] To the best of the authors' knowledge, no studies have interpreted test results in a standardized fashion.

The authors are also not aware of any study determining the optimal protocol for the MTT in patients with degenerative disease of the lumbar spine. Studies do suggest, however, that the additional information gained after 15min of walking time is negligible.[25, 41, 44] The intra-rater reliability of the MTT was high to excellent for both TTFS (ICC 0.90–0.98) and TAT (0.89–0.96) at 1.2mph or at an individually selected speed.[45] For an individual protocol with a gradual increase in walking speed, intrarater reliability was equally high (ICC 0.83).[42] As the MTT protocols differed between studies, reliability is unclear for other protocols. The total distance walked was significantly less in patients with LSS (mean 292±21m) than in a healthy control group (409±16m; $p<0.01$).[42] Convergent validity of the MTT was otherwise demonstrated with the self-paced walking test (SPWT; $r=0.88$),[46] self-reported walking distance ($r=0.62$),[33] as well as with self-reported symptoms of neurogenic claudication ($r=0.88$).[26] Other studies indicated a weak to moderate correlation between the objectively measured walking distance on the MTT with the walking distance that patients reported being able to walk.[23, 35] The MTT was shown to be sensitive to change in the postoperative setting.[44]

The MTT has been primarily studied in patients with LSS so far, and it was applied as an objective outcome measure in a number of RCTs and observational studies (Table 2). Despite a similar number of publications reporting on the MTT and the TUG test, the number of reported subjects was by far less for the MTT. In direct comparison to the SPWT, the MTT showed poorer internal responsiveness for LSS patients and patients consistently walked further in the SPWT.[23, 46] Also, a distinct drawback of the MTT is that special equipment (motorized treadmill) and trained personal is required, whereas other tests (e.g., TUG test, 6MWT) can be performed without additional resources. The potential risks of frightening or even injuring patients on a motorized treadmill must also be considered, especially when examining the elderly.[47]

The 5R-STS

For this test, participants are asked to sit down on an armless chair of standard height (48cm) and with a hard seat, firmly placed against the wall. With arms folded across the chest and feet kept flat on the ground (wearing stable footwear) participants are asked to stand up fully

and sit back down again without using the upper limbs and as fast as possible.[48] In order to increase discriminative capacity, most previous researchers have asked participants to perform five repetitions of the test, measuring the overall time to complete, with a maximum of 30 seconds.[18, 48-51]

The test result usually is the time to perform the five trials. Besides reporting raw values (in s), the 5R-STS was standardized and cut-off values have been proposed to discriminate between patients with lumber DDD and no (≤10.4s), mild (10.5–15.2s), moderate (15.3–22.0s) or severe OFI (>22.0s).[48] One study asked participants to perform as many repetitions of the STS test as possible within 30s; the test result being the total number of repetitions.[52] Other groups only measured the time required to rise from the chair (chair rise time), without sitting back down.[42, 51, 53]

The 5R-STS' intra-rater reliability was found to be high for a single (ICC 0.84)[42] and excellent for five repetitive trials (ICC 0.95–0.98).[18, 48] The test time for a single trial was significantly longer in patients with LSS (mean 0.99±0.16 sec) than in a healthy control group (0.57±1.72 sec; $p<0.01$).[42] For logarithmic 5R-STS test results, moderate convergent validity was reported in a cohort of n=157 patients with lumbar DDD in terms of RMDI (r=0.49), ODI (r=0.44), VAS back pain (r=0.31), and the EQ-5D index (r=-0.41; all $p<0.001$).[48] Age, body weight and the BMI were shown to influence the result of the 5R-STS test. A patient's expected "normal" test time (or "targeted 5R-STS performance" after successful treatment) can be predicted by the formula t_a = 0.03 age + 0.15 BMI + 1.7.[48]

The SPWT

For the SPWT, patients are instructed to walk continuously and at their own pace around an indoor 200m track, until they have to stop for back-related symptoms or other reasons. A maximum walking time limit of 30min has been proposed previously for patients that are little or asymptomatic.[23, 54, 55] Time is kept with a stop-watch and distance measured via a distance wheel or similar device. The main test result is the total walking distance (m), further results include total walking time (s), distance to first symptoms (DTFS) and walking speed (m/s). The intra-rater reliability was excellent for total walking distance (ICC=0.98), DTFS (ICC 0.94) and walking speed (ICC 0.80).[46, 55] In patients with LSS, total walking distance

ranged from 60–2065m (mean 776±726m, SD) and 67–1800s (mean 840±690s, SD).[54] The SEM and MCID of the SPWT have been reported to be 131 and 363m, respectively, in a small sample of 26 LSS patients.[55] The convergent validity with the MTT, self-estimated walking time and distance, as well as with symptoms of neurogenic claudication (back and leg pain, paresthesia, leg weakness, unsteadiness, ODI, SF-36 PCS and Swiss Spinal Stenosis Questionnaire (SSSQ)) were moderate to high.[23, 54] The SPWT outperformed the MTT in terms of internal (post-therapeutic) responsiveness, whereas external responsiveness (concordance with the patient's subjective perception of change in clinical status) was relatively poor for both tests.[23] Comparative studies between the two tests indicated that LSS patients walked a higher absolute distance in the SPWT (mean 987±914m) as compared to the MTT (mean 611±666m; $p<0.05$), probably as the SPWT allows for greater (self-selected) speed.[46] The SPWT also showed higher correlation with self-reported measures of pain, functional impairment and hrQoL than a digital activity monitor.[54]

The SWT

For the Shuttle Walking Test (SWT), participants are asked to walk a 10m course (32ft, 81in) on level ground and marked with cones at each end to complete one shuttle. Assistive devices (e.g., canes or walkers) are allowed if the participant normally uses them. The walking pace is monitored by a predetermined set of beeps from a sound-emitting device (CD-player, mp3-player, etc.), which indicate the amount of time allowed to walk one shuttle. The evaluation is progressive in that the time allowed between beeps for one shuttle gradually decreases. The test is maximal in that all participants are eventually unable to complete a shuttle in the allowed time, either for being short of breath or having too much pain or discomfort to continue. During the first minute of the test, beeps sound each 20s, and three shuttles (30m) are completed. During the second minute, four shuttles are completed; during the third minute five shuttles are completed; and so on up to 14 transits in 12 minutes, with a maximum total distance of 1020m.[56] The assessor counts the number of completed shuttles and the test result is the walking distance in meters (number of completed shuttles multiplied by 10).

The main test result is the total walking distance (m), for which excellent intra-rater reliability was reported (ICC 0.92-0.99).[56, 57] The SWT also demonstrated substantial changes in the functional status before and after surgery for LSS.[56, 57] For 95% certainty of change between two assessments in a single patient, the SWT should change by at least 76m.[56] In direct comparison with the MTT, the SWT exhibited similar test qualities for the assessment of patients with LSS, while evoking a lower level of cardiovascular stress.[58]

The 6MWT

The Six-Minute Walking Test (6MWT) is typically performed on a 3m wide and 30m long well illuminated flat hallway, according to the American Thoracic Society guidelines.[59] Patients are instructed to walk as fast as possible back and forth along the course for six minutes. Each minute, they are informed of the time and encouraged to continue. The main result of the test is the 6-minute walking distance (6MWD),[17, 60-62] traditionally documented by recording complete laps and using additional walkway marks every 3m for incomplete laps.[60, 62] Modifications with 5min walking time have been proposed,[51] but the majority of studies agree in the 6min assessment. Recently, a smartphone application has been programmed to allow measuring the 6MWD, as well as DTFS (m) and time to first symptoms (TTFS; s) in the patients home environment by GPS-coordinates (more information in Appendix B).[3]

The 6MWT is less explored than the SPWT, MTT or the SWT in the context of lumbar DDD. A previous study found the 6MWD to range around 357±107m in n=29 LSS patients (mean ODI of 30.7±16.3), with a similar 6MWD in n=27 healthy control subjects (mean 408±73m).[62] The authors noticed a 6MWD increase by 21m around 10 weeks and by 26m around one year postoperatively, but the result did not differ significantly from the baseline assessment. In a Swedish multi-center RCT, mean 6MWD in surgical candidates with LSS with or without spondylolisthesis was in the range of 309–331m and improved by 70–80m at two years postoperatively.[61] More available literature on the 6MWT derives from other medical fields. In populations with various chronic cardio-pulmonary diseases, the MCID for the 6MWD ranged between 14.0–30.5m.[63] The MCID currently remains to be determined for lumbar DDD and in particular for LSS.

The 6MWT appears useful in particular for its ease of administration using smartphone apps, but also because it closely resembles ambulatory activities in which patients with lumbar DDD are limited.[17]

Discussion

This article provides an overview of currently available objective measures of function, applied to patients with degenerative diseases of the lumbar spine. Systematic review of the available literature yields some interesting findings.

First, there was a significant and gradual increase in the reporting of objective measures of function over the last three decades. Second, there were a number of countries and scientific journals that appeared to be particularly interested in publishing research that employed objective measures of function. Third, and perhaps most important, we found that there was uncertainty pertaining to the reliability and validity of many of the objective measures applied in clinical studies. There was profound heterogeneity concerning the types of objective measure, their method of application, as well as regarding the definition of their main test results. Reporting of raw test values dominated the available literature and only few studies so far interpreted the results in a standardized fashion, adjusting for potential confounders such as age, BMI or gender. Given this variability across studies, comparison of cohorts in terms of OFI is currently limited.

Is there a current "gold standard"?

Based on the literature research there is no single "gold standard" for objective functional testing. Each physician and researcher must consider the type of function and impairment that is inherent to the patient he/she is going to examine. The TUG test, possibly combined with the 5R-STS test appears to be a reasonable choice, given both tests' ease of administration. They only require a chair and a stopwatch, allowing them to be performed spontaneously, e.g. in case OFI is suspected in an outpatient consultation in clinics. Both tests were found to be reliable and valid for patients with lumbar DDD.[6, 8, 48] The TUG test was shown to be particularly sensitive in patients with predominant lumboradicular pain (e.g., LDH),[8, 9, 15] whereas the 5R-STS test was more adequate in patients with predominant

LBP.[48] Longer and more challenging reliable and validated tests such as the SPWT, MTT or 6MWT may be chosen for LSS, considering that neurogenic claudication may not clinically manifest during examination with the shorter tests. For those planning to employ objective measures of function for research or clinical care, Table 2 summarizes existing options.

Opportunities for future research

There are some potential advantages of including objective measures of function in patient-care and research. Some of them, in particular the modern motion-sensor or smartphone-/GPS-based evaluations are a venue for passive and unobtrusive acquisition of longitudinal data, which could help overcome weaknesses inherent to current data collection such as missing data and loss of follow-up. Smartphones are integrated in virtually every aspect of our lives, having become a mirror of our behavior and likely very directly reflect change in behavior and loss of function, respectively. Further advantages include the usually high reliability versus high inter- and intra-observer variability of physician- and patient-rated measures, misinterpretation of questionnaire items and differences in the subjective scoring for educational, cultural and motivational reasons.[1] In contrast to subjective measures, objective outcome measures are applicable in foreign-language patients and illiterates. Presenting test-results as Z- or T-scores – expressing the patient's deviation from the healthy population norm – enables comparison between different tests and across studies/cohorts.[6] While PROM results are usually difficult to interpret for nonmedical personnel such as the patient, relatives or the public, result interpretation is more obvious for objective tests. Objective outcome measures comply with the modern trend of patient empowerment and patient-centered healthcare and research.[64] Lastly, objective measures of function are well accepted by patients.[16] Convergent validity between objective outcome measures and PROMs was consistently weak to moderate, indicating that objective measures cannot replace PROMs. These measures may add a further dimension to the comprehensive patient evaluation.[8, 20]

Need for standardization

This review revealed a variety of different assessments are available. For most the authors provided no reliability and validity measures. Even between studies that agreed on a similar type of objective measure, differences existed pertaining to the test protocol, definition of main outcome, and analytical approach. Also, objective tests of function can be heavily influenced by further neurological/orthopedic comorbidities (e.g., Parkinson's disease, previous stroke, hip/knee osteoarthritis), and not all prior studies accounted for this. Deyo et al. recommended the introduction of uniform standards for measuring PROM-based outcome about 20 years ago.[65] This review now indicates a need for agreement in terms of objective test selection, conduction and analysis, which should facilitate future comparison of study results across cohorts, studies and countries.

Strengths and limitations

To the best of the author's knowledge, there is no prior work that summarized currently available objective measures of function using a systematic approach. As such, this review may be a valuable resource for physicians when choosing one or several tests for patient care or research. Notwithstanding the systematic approach, additional articles may exist that we failed to identify. Furthermore, one may argue that excluding tests that measure certain aspects of the human body such as range of motion might be a weakness. However, this would have exceeded the scope of this article, and such a review was recently published.[66] Several studies included relatively low numbers of patients/subjects and more data on the objective measures of function will further increase our understanding of their specific value. Lastly, we were unable to perform a systematic assessment of the risk of bias in individual studies, since no validated tools to assess bias in systematic reviews of functional tests were available.

Conclusions

Clinical studies of patients with lumbar degenerative diseases increasingly employ objective measures of function, which offer high potential for patient-care and research. This review provides an overview on available options. Our findings call for an agreement and

standardization in terms of test selection, conduction and analysis to facilitate comparison of results across cohorts.

Conflicts of interest and funding

There was no conflict of interest and no funding was received for this study.

Appendix

A. The “TUG” app is available free of charge in multiple languages at the Apple App Store (https://itunes.apple.com/de/app/tug-app/id1119087707?mt=8) and Google Play (https://play.google.com/store/apps/details?id=ch.webgearing.tugapp).
B. The “6MWT” app will soon be available for smartphones and can then be downloaded free of charge in the Apple App Store (https://itunes.apple.com/us/app/6wt/id1454002232) or Google Play (https://play.google.com/store/apps/details?id=ch.webgearing.tugapp) in multiple languages, including English, German and French (more detailed information on the 6MWT app will follow during the review process, once the final version has been uploaded in the app stores).
C. Medline (Pubmed) search terms: ("goals"[MeSH Terms] OR "goals"[All Fields] OR "objective"[All Fields]) AND ("Assessment"[Journal] OR "assessment"[All Fields]) AND ("physiology"[Subheading] OR "physiology"[All Fields] OR "function"[All Fields] OR "physiology"[MeSH Terms] OR "function"[All Fields]) AND ("lumbar vertebrae"[MeSH Terms] OR ("lumbar"[All Fields] AND "vertebrae"[All Fields]) OR "lumbar vertebrae"[All Fields] OR ("lumbar"[All Fields] AND "spine"[All Fields]) OR "lumbar spine"[All Fields])
D. SCOPUS search terms: objective AND assessment AND function AND lumbar AND spine
E. EMBASE search terms: 'objective assessment function lumbar spine' OR (objective AND ('assessment'/exp OR assessment) AND ('function'/exp OR function) AND lumbar AND ('spine'/exp OR spine))
F. Web of Science search terms: TOPIC: (objective assessment function lumbar spine)

Tables:

Table 1: Table detailing the inclusion and exclusion criteria, according to the PICOS (participants, interventions, comparators, outcomes, and study design) approach detailed in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement. An additional category, "Publications," was added to primarily encompass the language restrictions.

	Inclusion criteria	Exclusion criteria
Participants	• Human subjects/patients with lumbar degenerative disc disease • Clinical setting	• Animal subjects • Laboratory setting
Interventions	No intervention required	No intervention required
Comparators	No comparator required	No comparator required
Outcomes	• Objective measure, reflecting functional (dis)ability of a patient/human subject Reporting at least one of the following: • Test quality or feature (Agreement, reliability, validity, minimum clinically important difference, etc.) • Correlation with any subjective outcome measure • Satisfaction with outcome measure • Objective outcome measure used to determine therapeutic effect of a health-care intervention	Either of the following: • No report of any objective test of patient/human subject function • Report of radiological outcomes, electrophysiological or kinematic function of the spine (e.g., electromyography or range of motion) only • Outcome data not sufficiently presented or provided upon request from the authors
Study design	Either of the following: • Randomized controlled trial • Quasi-experimental study • Observational study	Either of the following: • Study protocols • Secondary research (review or meta-analysis of primary research)
Publications	Either of the following: • English language • German language • French language	Either of the following: • Conference abstract • Letter, comment or note

Table 2: Comprehensive list of the objective tests that were applied, together with a brief description, the disease type, study type and objective, number of reported patients and scientific value (estimated by the cumulative impact factor (IF) of publications.

No.	Name of objective test	Absolute and relative frequency	Brief description	Study types	Disease types studied	Study objective	Number of reported subjects* (cumulative; mean (SD))	Journal IF (cumulative; mean (SD))	References
1	TUG test	N=26; 31.7%	Participants begin with sitting on a chair. On the word "Go," they get up and walk as fast as possible to a marked line on the floor at 3m distance. At this line, patients turn around, return to the chair and sit down again as quickly as possible. The test result is the time between getting up and sitting down again (s), using a stopwatch or the smartphone "TUG app". Transformation of raw test values into age- and sex-standardized T-scores to determine OFI is recommended.[6, 8]	RCT (n=2), prospective observational (n=23), retrospective (n=1)	LSS (n=19); LDH (n=16); LBP (n=17); listhesis (n=14); deformity (n=2); VCF (n=1); other (n=2)	Test characteristics (n=10); disease characteristics (n=11); outcome measure (n=5)	5181; 199 (141)	69.55; 2.78 (1.11)	[6-21, 49, 50, 52, 67-73]
2	MTT	N=25; 30.5%	Patients walk on a treadmill, usually at a predefined protocol. Different studies have proposed different protocols in terms of speed, time or incline and there is no clearly superior or "gold standard" program (see article text). Test results are the time of onset or significant increase in symptoms (s), the total ambulation time (s), the total distance walked (m), as well as the maximum walking speed (m/s) for protocols that allow individual speed selection.	RCT (n=5); prospective observational (n=19), retrospective (n=1)	LSS (n=24); LDH (n=1); LBP (n=3); listhesis (n=1); other (n=1)	Test characteristics (n=6); disease characteristics (n=12); outcome measure (n=6)	1499; 60 (42)	65.21; 2.61 (1.52)	[22-37, 39-46, 74]
3	5R-STS test	N=9; 11.0%	Participants sit down on an armless chair (standard height) with a hard seat, firmly placed against the wall. With arms folded across the chest and feet kept flat	RCT (n=2); prospective observational (n=6),	LSS (n=8); LDH (n=2); LBP (n=3); listhesi	Test characteristics (n=4); disease characteristics	955; 106 (75)	24.94; 2.77 (1.08)	[18, 28, 42, 48-53]

			on the ground participants then stand up fully and sit back down again without using the upper limbs.[18, 48] The test result is the time needed until the complete standing position is reached (s). In order to increase discriminative capacity, previous researchers usually asked patients to perform five repetitions of the test, measuring the overall time to complete, with a maximum of 30 seconds (5R-STS).[18, 48-51]	retrospective (n=1)	s (n=1)	(n=3); outcome measure (n=2)			
4	Accelometry analysis	N=9; 11.0%	A number of studies have applied various wearable devices on the body (usually throughout the day only) that measure acceleration and filter these raw acceleration data into a metric known as activity counts, representing the intensity of physical activity. Some devices include further functions such as altimeters. Depending on the device, the number of steps taken, distance walked (m), or calories expended can be calculated. There is a body of literature supporting that accelerometers are reliable and provide a valid indicator of overall physical activity in adults.	Prospective observational (n=7), retrospective (n=2)	LSS (n=8); LDH (n=2); LBP (n=2)	Test characteristics (n=2); disease characteristics (n=5); outcome measure (n=2)	336; 37 (23)	22.22; 2.47 (1.13)	[36, 54, 75-81]
5	SPWT	N=8; 9.8%	Patients walk continuously at their own pace around a 200m track, until they have to stop for back-related symptoms or other reasons. Time is kept with a stop-watch and distance measured via a distance wheel or similar device. The main test result is the total walking distance (m), further results include TAT (s), DTFS and walking speed (m/s).[46]	Prospective observational (n=8)	LSS (n=8); deformity (n=1)	Test characteristics (n=4); disease characteristics (n=2); outcome measure (n=2)	388; 49 (55)	22.45; 2.81 (0.74)	[23, 46, 54, 55, 79, 80, 82, 83]
6	Gait anal	N=7; 8.5%	Gait analyses have been performed using	Prospective	LSS (n=5);	Test characteri	293; 42	14.89; 2.13	[40, 53, 62, 72, 81,

	ysis		walkways containing pressure sensors,[53] reflective markers on participants and infrared cameras,[40, 72, 84] infrared-emitting diodes on participants captured by motion analysis systems,[85] inertial sensors [62] or sensor-equipped smart shoes [86] to calculate spatiotemporal parameters, such as walking velocity, stride length, step width, gait cycle times (on defined gait cycles) among others. Usually several barefoot gait cycles are performed per participant. The systems were reported as reliable and valid for spatiotemporal parameters.[53, 62]	observational (n=7)	LDH (n=3); LBP (n=3); listhesis (n=2); other (n=3)	stics (n=3); disease characteristics (n=1); outcome measure (n=3)	(16)	(0.70)	84, 85]
7	10m walking test	N=6; 7.3%	For the 10- or 15m walking test, participants are instructed to walk (at a comfortable [87] or at maximum speed [51, 88, 89]) on a flat, straight 10- or 15m walkway.[17] Most groups have used a 10m distance; the 15m distance was used once.[51] The test result is the time to complete the selected distance (s).[17, 88, 89] One group evaluated patients by their ability to run rather than walk the distance of 10m.	Prospective observational (n=6)	LSS (n=4); LBP (n=1); deformity (n=1)	Test characteristics (n=1); disease characteristics (n=4); outcome measure (n=1)	250; 42 (14)	16.62; 2.77 (0.63)	[17, 51, 86-89]
8	SWT	N=5; 6.1%	Participants walk a 10m course on level ground and marked with cones at each end to complete one shuttle. Assistive devices are allowed if the participant normally uses them. The walking pace is monitored by a predetermined set of beeps from a sound-emitting device, which indicate the amount of time allowed to walk one shuttle. The evaluation is progressive in that the time allowed between beeps for one shuttle gradually decreases. All participants are eventually unable to	RCT (n=2), prospective observational (n=3)	LSS (n=3); LBP (n=2)	Test characteristics (n=2); disease characteristics (n=1); outcome measure (n=2)	954; 191 (199)	31.96; 6.39 (9.53)	[47, 56, 57, 90, 91]

			complete a shuttle in the allowed time. The test includes a maximum of 14 transits in 12 min, with a maximum total distance of 1020m.[56] The assessor counts the number of completed shuttles and the test result is the walking distance (m; number of completed shuttles multiplied by ten).						
9	6MWT	N=5; 6.1%	Participants walk as fast as possible back and forth along a flat hallway for six minutes. They are informed of the time and encouraged each minute. The main result of the test is the 6MWD (m),[17, 60-62] traditionally documented by recording complete laps and using walkway marks for incomplete laps.[60, 62] A smartphone application has been programmed to measure the 6MWD, as well as TTFS and DTFS more conveniently using GPS-coordinates.[3]	RCTs (n=1), prospective observational (n=4)	LSS (n=2); listhesis (n=1); deformity (n=2)	Test characteristics (n=1); disease characteristics (n=1); outcome measure (n=3)	518; 104 (88)	90.73; 18.15 (34.16)	[17, 51, 60-62]
10	Bicycle ergometer test	N=3; 3.7%	Participants sit in their preferred posture on a stationary bicycle ergometer, holding the handlebars with both hands. Throughout the entire test, they are instructed to continue at a constant pedaling speed of 50–60rpm. No resistance is added for the first minute, but resistance is increased to 20W (≈150kpm/m) for the second, and to 50W (≈300kpm/m) for additional eight minutes. The total maximum test time is 10min, if the patient does not have to stop earlier. The test result is the time that the patient pedaled (s), as well as the total distance (m). Pain and/or paresthesia can be measured before and after the test; the TTFS can also be monitored.	Prospective observational (n=3)	LSS (n=3)	Test characteristics (n=1); disease characteristics (n=2)	124; 41 (18)	7.63; 2.54 (2.43)	[26, 27, 29]
11	6m walk	N=3; 3.7%	Participants complete timed walks over a 6m	Prospective	LSS (n=2);	Disease characteri	256; 85	10.42; 3.47	[18, 50, 92]

	ing test		walkway at their preferred speed. Having ample space before and after the walking space is required to ensure that walking speed is constant.[18] The main test results is the time (s) taken to complete the walk (single trial [18, 50] or mean of six trials [92]), whereas number of steps, walking velocity and cadence have also been analyzed.[92]	observational (n=2), retrospective (n=1)	LBP (n=1)	stics (n=2); outcome measure (n=1)	(38)	(1.18)	
12	AST	N=2; 2.4%	For the alternative step test (AST), the entire left and right foot (shoes removed) alternatively have to be placed as fast as possible onto a step with a distinct height (e.g. 18cm) and depth (e.g. 40cm). The time taken to take eight steps comprises the test measure (s). The AST is used to evaluate a participant's ability to maintain standing balance while performing a potentially destabilizing activity, such as standing on one leg while stepping.	Prospective observational (n=1), retrospective (n=1)	LSS (n=2)	Disease characteristics (n=2)	206; 103 (32)	7.63; 3.82 (1.45)	[18, 50]
13	WC test	N=2; 2.4%	For the weight carrying (WC) test participants walk 20m as fast as possible while carrying 10% of their body weight evenly distributed in hand-held weights. The test result is the time needed to complete the distance (s).	RCT (n=1), prospective observational (n=1)	LSS (n=2)	Test characteristics (n=1); outcome measure (n=1)	182; 91 (88)	5.87; 2.93 (0.20)	[28, 42]
14	Single leg balance	N=2; 2.4%	Participants maintain single-leg balance, unsupported, for as long as possible (maximum of 30s). The test result is the time until failing to keep balance (s).	Prospective observational (n=2)	LSS (n=1); deformity (n=1)	Test characteristics (n=1); disease characteristics (n=1)	180; 90 (49)	3.98; 1.99 (1.18)	[14, 70]
15	GPS-based assessment	N=2; 2.4%	GPS is used to track position- and movement data of participants during the day in intervals of about 10s. Outcomes include total distance walked, average distance, walking speed and total walking duration per day. Precision of measurements of about ± 1.5m outside (optimal	Prospective observational (n=1)	LSS (n=1); LDH (n=1); LBP (n=1)	Test characteristics (n=1); disease characteristics (n=1)	6; 3 (1)	5.43; 2.71 (0.11)	[93, 94]

			conditions) have been reported.[93] The data have to be pre-processed using complex algorithms and checked for plausibility.						
16	Balance test	N=1; 1.2%	This test requires an industrial force plate balance platform, designed for testing postural stability/trace length, indicating how far the participant shifts from the center of pressure over a 20s period while performing balance tasks. The test result is the participant's shift (mm^2).	Prospective observational (n=1)	LSS (n=1)	Disease characteristics (n=1)	10	3.12	[80]
17	Fast stair descent	N=1; 1.2%	Participants are timed as they descent twelve steps with a defined depth (e.g. 28cm) and height (e.g. 17cm) "as quickly and as safely as possible". The test result is the time (s) and an average of two trials is calculated.	Prospective observational (n=1)	LBP (n=1)	Disease characteristics (n=1)	106	3.08	[13]
18	Gait speed	N=1; 1.2%	Participants walk 2.44m at their usual (self-selected) pace, providing space for acceleration and deceleration.	Prospective observational (n=1)	LBP (n=1)	Disease characteristics (n=1)	106	3.08	[13]
19	Sitting and standing time	N=1; 1.2%	Participants sit and stand as long as possible. The test result is the maximum duration (min) for sitting (mean: 122–130min) and standing (mean: 10–20min).	Prospective observational (n=1)	LSS (n=1); deformity (n=1)	Outcome measure (n=2)	179	3.12	[82]
20	One minute stair climbing	N=1; 1.2%	Participants walk up and down a staircase with five stairs for 1min. The test result is the number of stairs climbed during the time period.	Prospective observational (n=1)	LBP (n=1)	Test characteristics (n=1)	53	2.93	[51]
21	PILE	N=1; 1.2%	For the progressive isoinertial lifting evaluation (PILE) participants lift a box with a weight four times within 20s from the floor up to a 75cm-high table. Starting weights and incremental weights are different for men and women. The starting weight for women is 3.6 kg and 5.85 kg for men (weight of box included). After each completed lifting cycle, the weight	Prospective observational (n=1)	LBP (n=1)	Test characteristics (n=1)	53	2.93	[51]

			for women is increased by 2.25 kg and for men by 4.5 kg. The test stops when the participant cannot lift the box four times within 20s, the participant decides to stop, the heart rate exceeds 85% of the maximal heart rate, the maximal amount of the weight that could safely be lifted is reached (60% of participant's body weight), or the test observer considers further lifting unsafe. The test result is the number of fully completed lifting stages.						

1 * Subjects include both patients and controls.

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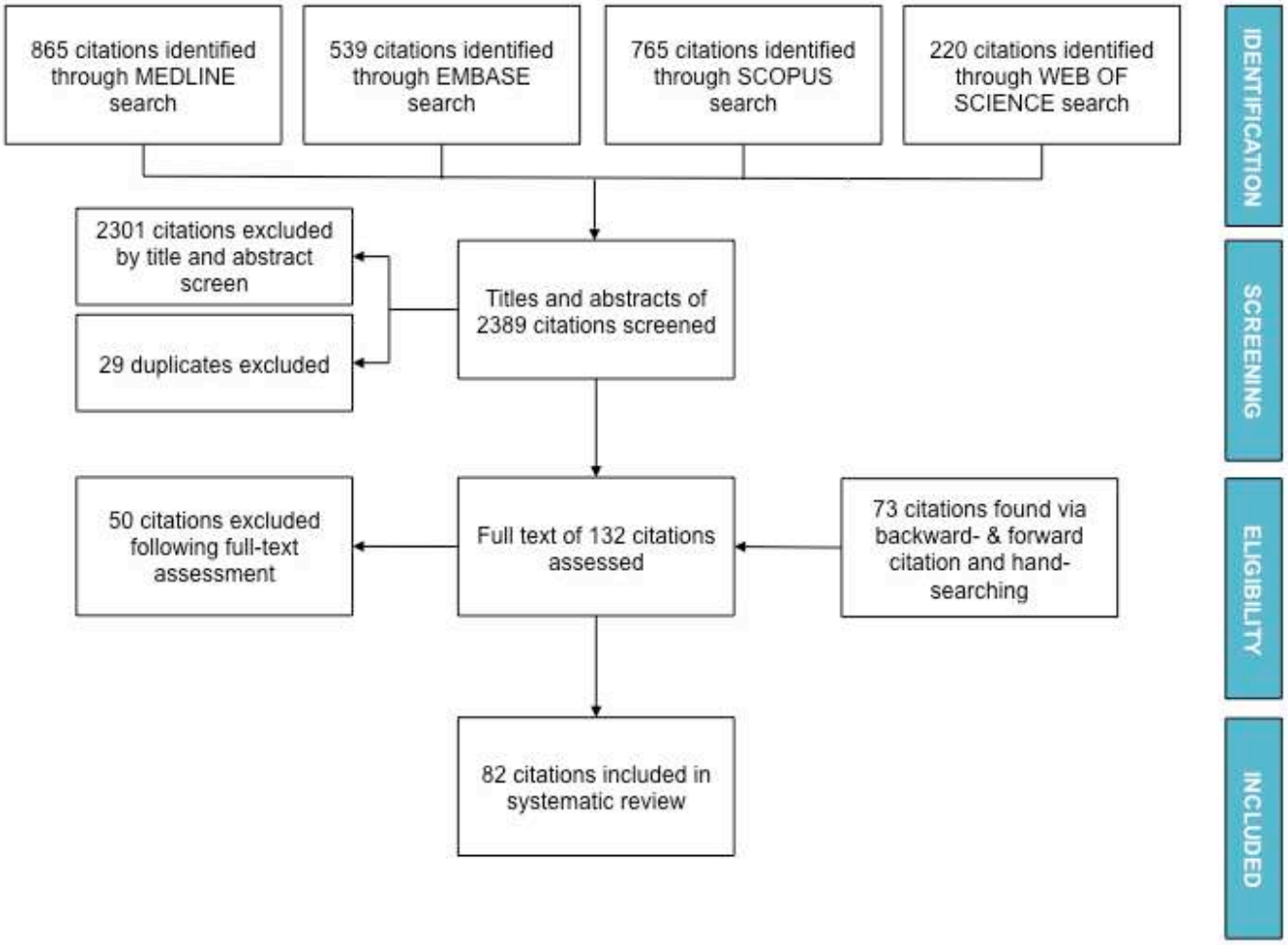
Figure legends

Figure 1: PRISMA flowchart detailing the process for the selection of papers.

Figure 2: Line graph highlighting the significant ($p<0.001$) annual increase in the number (#) of publications (y-axis) over the last decades (x-axis).

Figure 3: Histogram indicating the number (#) of publications (y-axis) that employed an objective measure of function per country (x-axis).

Supplemental Figure 1: Histogram indicating the number (#) of publications (y-axis) that employed an objective measure of function per scientific journal (x-axis).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539 citations identified through EMBASE search
765 citations identified through SCOPUS search
220 citations identified through WEB OF SCIENCE search
2301 citations excluded by title and abstract screen
29 duplicates excluded
Titles and abstracts of 2389 citations screened
50 citations excluded following full-text assessment
Full text of 132 citations assessed
73 citations found via backward- & forward citation and hand-searching
82 citations included in systematic review
IDENTIFICATION
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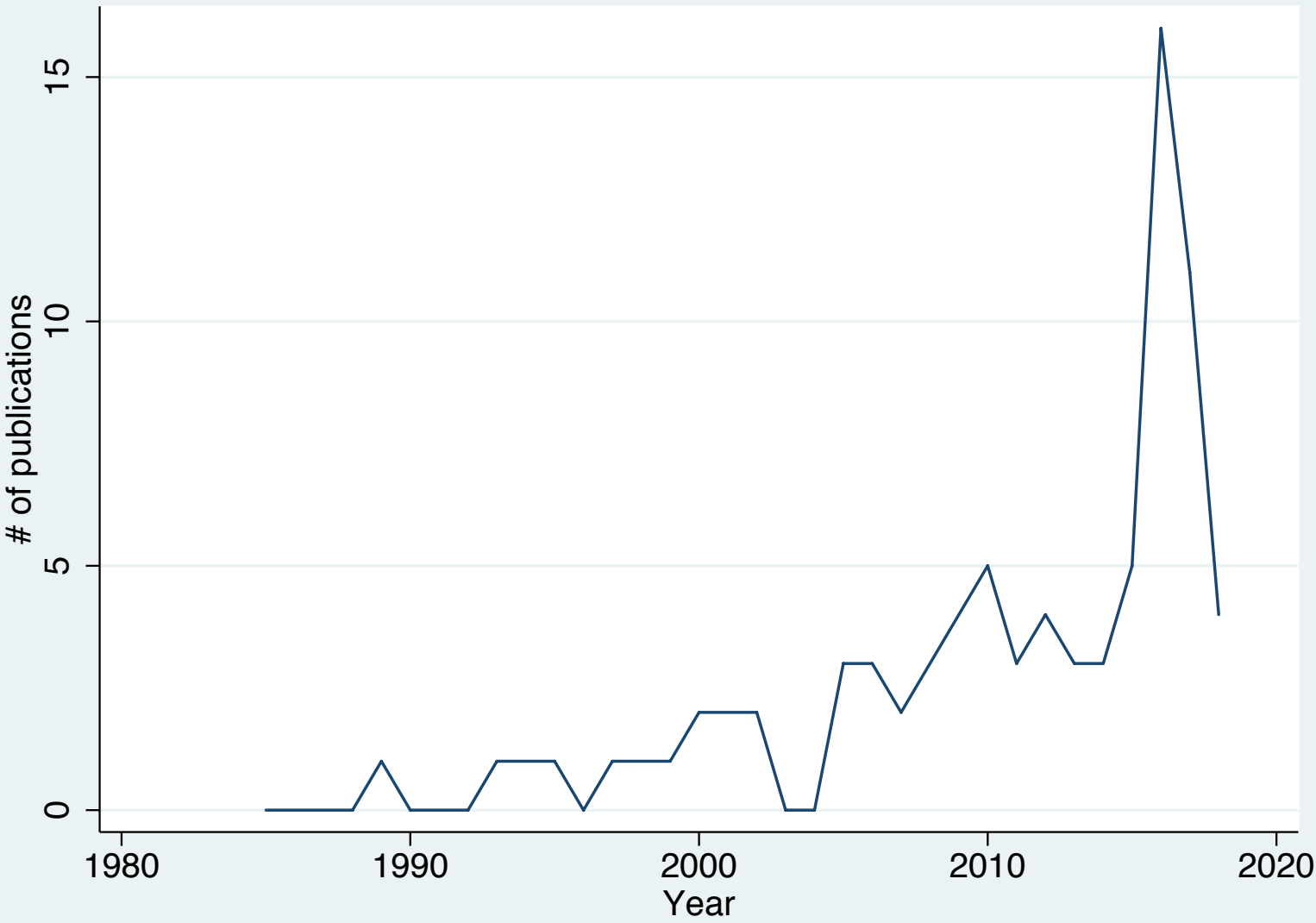
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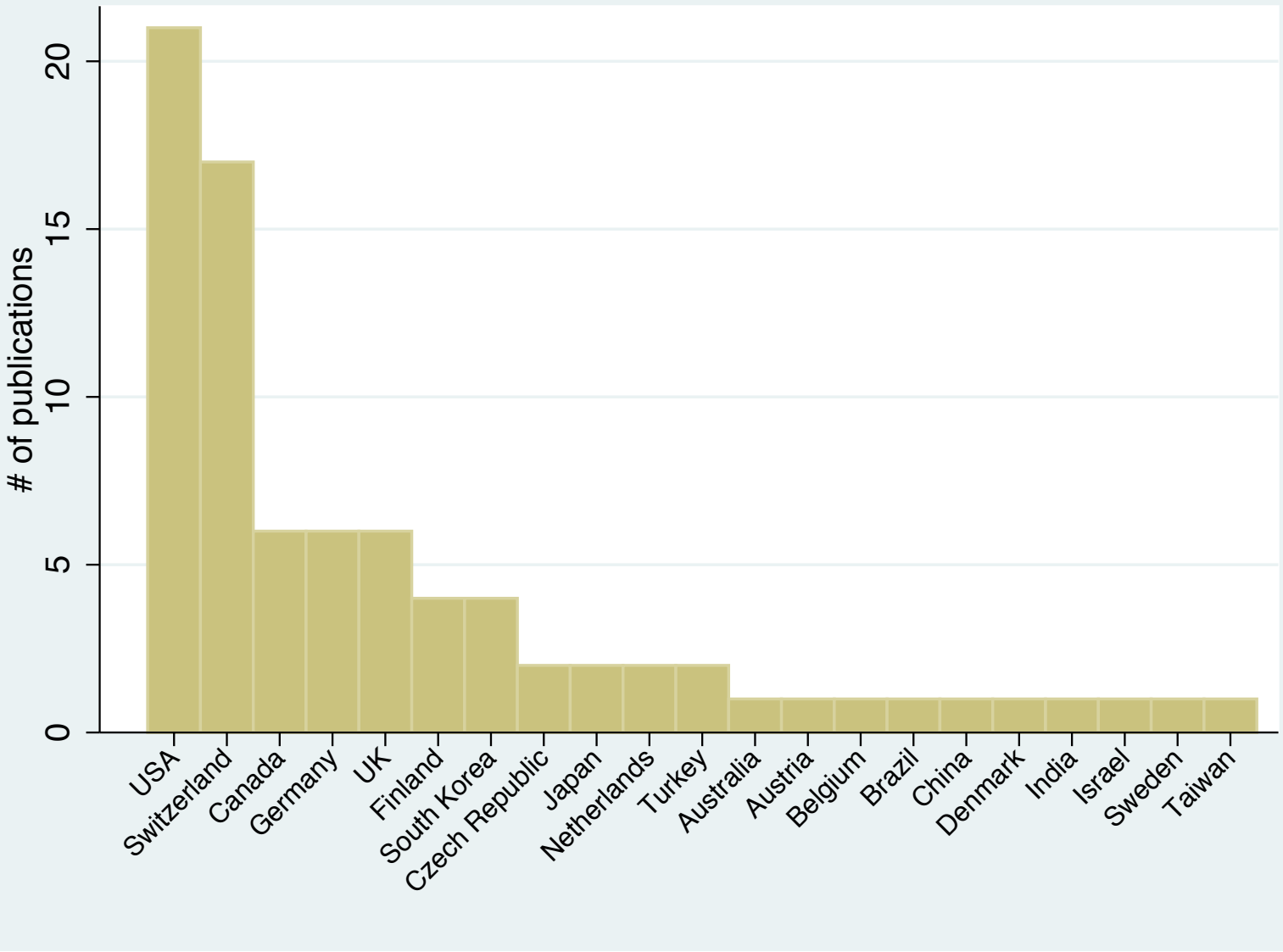
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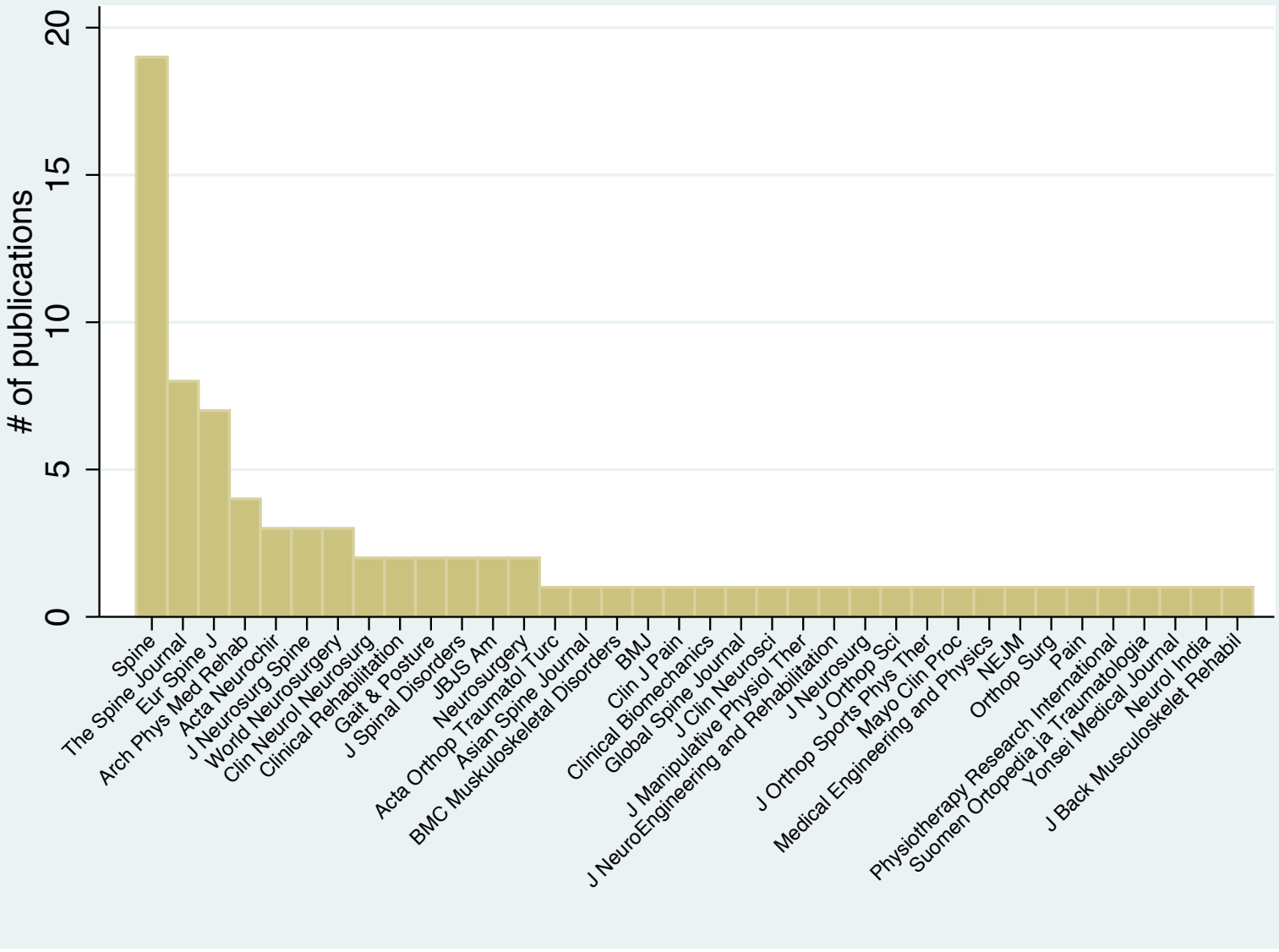
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Spine
The Spine Journal
Eur Spine J
Arch Phys Med Rehab
Acta Neurochir
J Neurosurg Spine
World Neurosurgery
Clin Neurol Neurosurg
Clinical Rehabilitation
Gait & Posture
J Spinal Disorders
JBJS Am
Neurosurgery
Acta Orthop Traumatol Turc
Asian Spine Journal
BMC Musculoskeletal Disorders
BMJ
Clin J Pain
Clinical Biomechanics
Global Spine Journal
J Clin Neurosci
J Manipulative Physiol Ther
J NeuroEngineering and Rehabilitation
J Neurosurg
J Orthop Sci
J Orthop Sports Phys Ther
Mayo Clin Proc
Medical Engineering and Physics
NEJM
Orthop Surg
Pain
Physiotherapy Research International
Suomen Ortopedia ja Traumatologia
Yonsei Medical Journal
Neurol India
J Back Musculoskelet Rehabil